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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,935	04/04/2000	Maria Palasis	02844/56301	5876

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/542,935

Applicant(s)

PALASIS, MARIA

Examiner

Brian Whiteman

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): 112 second paragraph rejection for claims 17, 30, and 37.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1, 3, 10-12, 17-20, 23-27, 30, 34-38, 42-44, 47, 49-52, 54-56, 58 and 59.Claim(s) withdrawn from consideration: None.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments that priority to US 09/204,254 now US Patent 6,369,039 should be afforded benefit of the earlier filing date is not found persuasive. It is acknowledged that the specification of '039 list various therapeutic agents that can be in the coating. However, as stated in the Final Rejection, nothing in the specification of '039 would lead one to the particular combination as set forth in the claims. The applicants stating that the specification of '039 provides a list of therapeutic agents and that the preceding agents can be used in combination does not lead one to the particular combination as set forth in the claims.

Applicant's argument that the 112 first paragraph new matter rejection should be withdrawn because Example 7 discloses a first therapeutic agent comprising a vector containing a first polynucleotide encoding VEGF and a second polynucleotide encoding Fas ligand. In addition, applicant argues that pages 22-23 provide support the previously amended claims. The passage is directed to localized development and expansion of blood vessel and does not provide support for the previously amended claims 1 and 26. The passage does not provide support for using a polynucleotide encoding an angiogenic agent and a non-genetic therapeutic agent. In addition, neither the first nor second polynucleotide in example 7 provide support for the previously amended claims 1 and 26. Both are genetic therapeutic agents. The example does not provide support for previously amended claims 1 and 26.

Applicant's arguments that the 112 second paragraph rejection for the term "small molecule" in claim 50 should be withdrawn because the term of art that refers to compounds synthesized using techniques such as combinatorial chemistry for use as a library from which candidate lead compounds can be isolated for activity in a particular biological assay and more information on such molecules can be obtained from the internet is not found persuasive. The specification does not provide the definition of the term used in the argument. There is not support or guidance in the specification that would lead one skilled in the art to the term provided in the argument or the website cited in the argument for information on small molecules. A small molecule could be any molecule that cannot be observed by the naked eye, e.g., DNA, RNA, protein, organic compound, inorganic compound. The specification does not claim or particularly point out what is the definition for the term.

Applicant's argument that the 112 second paragraph rejection for term "site specific" in claims 52 and 56 should be withdrawn because the term is a term of art that refers to the particular locus of an endogenous DNA strand, for example a chromosome, wherein an exogenous DNA for example vector polynucleotides such as viral DNA or transposable DNA will integrate. The specification does not provide a definition of the term and nothing in the specification would lead one skilled in the art to the term set forth in the applicant's argument. In addition, there is no support or guidance in the specification that would lead one skilled in the art to the article cited in the argument for support for the definition of the term.

Applicant's argument that the 102(b) rejection for claims 1, 10, 11, 19, 24, 26, 34, 35, 37, 44, 49, 50, 52, 56, 58, and 59 should be withdrawn is not found persuasive. As stated in the Final Rejection, Isner teaches a method of delivery of an angiogenic factor combined with other genes or their encoded gene products (col. 1, line 66-column 2, line 7 and col. 7, lines 1-14). Applicants traverse that none of the other genes are listed as "angiogenic protein" as defined by Isner (Col. 3, lines 40-42). However, nitric oxide synthase is an angiogenic agent and applicants have provided no evidence that nitric oxide synthase is not an angiogenic agent. Thus, the claims remain anticipated by Isner.

Applicants argument that the 103(a) rejections should be withdrawn for the same reasons as set forth under the 102(b) argument is not found persuasive. The argument is not found persuasive for the same reasons set forth above for maintaining the 102(b) rejection.

*Scott D. Pritch*

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PATENT EXAMINER